Valutazione economica dell'uso dell'abciximab come preparazione all'angioplastica coronarica nel contesto sanitario italiano [An economic assessment of the use of abciximab as a coronary angioplasty preparation in the Italian health-care context]

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Abciximab (anti-glycoprotein IIb/IIIa drug) as a pre-treatment to prevent thrombotic events in patients undergoing percutaneous transluminal coronary angioplasty (PTCA).

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population elective patients undergoing PTCA who might be at high risk of thrombotic events leading to death, myocardial infarction, repeated PTCA or bypass surgery.

Setting
The study setting was a hospital. The economic study was mainly undertaken in the Campo di Marte hospital, Lucca, Italy.

Dates to which data relate
Effectiveness evidence was derived from three studies published between 1994 and 1997. The resources used were based on the relevant Italian Diagnosis Related Groups (DRGs). No price year was reported.

Source of effectiveness data
Effectiveness data were obtained from a meta-analysis of three studies that evaluated the efficacy and safety of abciximab.

Outcomes assessed in the review
The review of the three clinical trials assessed single end-points, such as the incidence of death, myocardial infarction, repeated PTCA and bypass surgery in patients who received abciximab and placebo. A final end-point, based on the aggregation of the single end-points, was also considered and relative risk (with confidence intervals) was reported. Finally, the proportion of event-free patients at 6 months of follow-up, and adverse events in the two groups were reported.

Study designs and other criteria for inclusion in the review
Three randomised controlled trials were included in the review: EPIC, EPILOG and CAPTURE. The trials had large sample sizes (1,404, 2,792 and 1,265 patients respectively) and patients were followed for 6 months.

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
All the studies included in the review used blinded assessment of patients. The sample size of each of the three primary studies was very large.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
Three studies were used to derive the effectiveness data used for the cost-effectiveness analysis.

**Methods of combining primary studies**
A meta-analysis was performed to combine the results in terms of thrombotic events that occurred in three clinical trials. The relative risk of abciximab compared to placebo was calculated as well as a 95% confidence interval.

**Investigation of differences between primary studies**
All the trials compared abciximab to a placebo, but each trial analysed different doses of abciximab or different combinations of abciximab and heparin.

**Results of the review**
After six-months of follow-up the cumulative incidence of thrombotic events (final end-point) found in the three trials was 29.87% (678/2270) for the placebo group and 25.04% (799/3191) for the abciximab group.

The relative risk of abciximab pre-treatment with respect to the placebo was estimated to be 0.84 (95% CI: 0.77 - 0.91).

With respect to the single end-points, the incidence of death was 2.38% (placebo) compared to 1.94% (abciximab). The incidence of myocardial infarction was 9.91% (placebo) versus 5.8% (abciximab). The incidence of bypass surgery was 7.66% (placebo) versus 6.33% (abciximab) and the incidence of repeated PTCA was 17.53% (placebo) versus 14.82% (abciximab).

The cumulative incidence of adverse events was 4.93% in the placebo group and 6.6% in the abciximab group.

**Measure of benefits used in the economic analysis**
The number of avoided thrombotic events per 100 patients was used as the measure of benefit. These data were obtained from the meta-analysis of the trials.

**Direct costs**
The cost of the treatment was estimated for a standard patient (3 doses of 10 mg per patient).

The cost of each event and procedure was obtained on the basis of Italian DRGs:
cost of death was DRG123;

cost of myocardial infarction was 50% of DRG121 + 50% of DRG122;

cost of PTCA was DRG112;

cost of bypass surgery was DRG106.

As regards adverse events, the cost of intracranial haemorrhage was taken from DRG16 and DRG17. No discount rate was applied given the short time horizon of the analysis (6 months). Unit costs and frequency of the events were reported separately. Total costs for 100 patients were then calculated. No price year was reported.

Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
Indirect costs were not included.

Currency
Italian Lira (L). No conversion was undertaken.

Sensitivity analysis
A one-way sensitivity analysis was performed on the relative risk of abciximab compared to placebo. The relative risk value was varied according to the range suggested by the 95% confidence interval.

Estimated benefits used in the economic analysis
74.96% of patients were event-free (no thrombotic events) after 6 months of follow-up in the abciximab group and 70.13% were event free in the placebo group. The difference (4.83%) was statistically significant.

Cost results
The cost of abciximab for a standard patient was estimated to be L2,561,100, the cost of PTCA L6,435,000 and the cost of bypass surgery L30,205,000. Finally the cost of myocardial infarction, death and intracranial haemorrhage were estimated to be L7,507,000, L6,192,000 and L4,989,000 respectively. Total costs, for both the placebo and the abciximab group, were multiplied by the frequency of events per 100 patients. The total costs per 100 patient in the placebo and in the abciximab group were estimated to be L1,078 million and L1,244 million respectively. The difference in total costs between the abciximab and the placebo group was L165 million per patient.

Synthesis of costs and benefits
Costs and benefits were combined by performing an incremental cost-effectiveness analysis. The incremental cost-effectiveness of abciximab compared to placebo was estimated to be L34,269,741 per avoided event. A sensitivity analysis was conducted on the relative risk of abciximab with respect to placebo (0.84), on the basis of the 95% confidence interval (0.77-0.91). With a value of relative risk equal to 0.77, the incidence of thrombotic event in the abciximab group would drop to 23% and the incremental cost-effectiveness ratio would fall to L24.2 million per avoided event. With a value of relative risk equal to 0.91, the incidence of events in the abciximab group would increase to 27.18% and the incremental cost-effectiveness ratio would go up to L61.5 million per avoided event.

Authors' conclusions
The authors concluded that abciximab is likely to be a cost-effective pre-treatment for patients undergoing PTCA, in particular for individuals characterised by a high-risk of thrombotic events.

**CRD COMMENTARY - Selection of comparators**
The authors compared abciximab with a "do nothing" alternative. In reality, abciximab is not the only anti GP-IIb/IIIa drug that could be used to prevent thrombotic events for patients undergoing PTCA. The authors themselves stated that it would be interesting to evaluate the effectiveness, safety and cost-effectiveness of other, less expensive, anti GP-IIb/IIIa drugs

**Validity of estimate of measure of effectiveness**
Effectiveness evidence was obtained from a meta-analysis of published randomised controlled trials, but few details were provided on the way in which this analysis had been performed. It would have been useful to have had more information about the sources used to identify the primary studies and the methods used to combine them.

**Validity of estimate of measure of benefit**
Health benefits were extrapolated from the same sources used to obtain effectiveness evidence, raising the same issues considered for the measure of effectiveness.

**Validity of estimate of costs**
The costs of each event and procedure were based on DRGs that are only an approximation of the average cost and resource use per patient in each group. In particular in the case of myocardial infarction and death it is very difficult to estimate an average cost per patient. Therefore, a sensitivity analysis would have been useful to increase the robustness and the validity of the results of the analysis.

**Other issues**
The authors compared the results of their work with three published studies (Spanish, Dutch and Italian) that assessed the cost-effectiveness of abciximab as pre-treatment for patients undergoing PTCA. The results of these studies were substantially similar to those found by the authors. This comparison strengthens both the validity and the generalisability of the results obtained in the present analysis.

It might also have been interesting to have investigated the cost-effectiveness of abciximab in a sub-group of patients receiving PTCA who might have a different risk of thrombotic events. For example, patients with permanent angina compared to patients with acute coronary syndrome.

**Implications of the study**
The authors suggested that the use of abciximab as pre-treatment for patients undergoing PTCA is likely to be a cost-effective strategy in the context of Italian local health agencies (USL).

**Source of funding**
None stated.

**Bibliographic details**
Other publications of related interest


Indexing Status

Subject indexing assigned by NLM

MeSH
Angioplasty, Balloon, Coronary /economics /methods; Antibodies, Monoclonal /adverse effects /economics /therapeutic use; Clinical Trials as Topic; Coronary Disease /economics /mortality /therapy; Drug Costs; Humans; Immunoglobulin Fab Fragments /adverse effects /economics /therapeutic use; Incidence; Italy /epidemiology; Platelet Aggregation Inhibitors /adverse effects /economics /therapeutic use; Sensitivity and Specificity; Treatment Outcome

AccessionNumber
21999006690

Date bibliographic record published
28/02/2002

Date abstract record published
28/02/2002